REMARKS

Claims 13-22 remain for consideration in this application, claims 1-12 having been withdrawn from consideration. Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Assistant Commissioner is authorized to deduct the fees from the Monsanto Company Deposit Account No. 13-4125. Corrections to the Drawing Figures have been sent by separate mailing to the Official Draftsperson and a copy of the corrected drawings have been attached hereto for the Examiner's file. Applicants respectfully request reconsideration of the claims as amended and in view of the following remarks.

Status of Restriction Requirement

Applicants acknowledge the decision of the Examiner to make Final the restriction requirement.

Status of Drawings

Applicants have corrected the drawing figures 16A-E and have forwarded such to the Official Draftsperson. A courtesy copy is enclosed herewith for the Examiner.

35 U.S.C. § 112, first and second paragraph rejection

While not acknowledging the correctness of the Examiner's rejection, Applicants have amended the claims as set forth above to clarify any potential indefiniteness in the claims. It is believed that claim 13 has been clarified and contains the step required by the Examiner. Regarding claim 18, the Examiner's attention is drawn to page 18, line 28 through page 19, lines 1-6 for support of the term "region of homology." This is a term of art in the field of plastid transformation and is well known and understood by the skilled artisan.

Regarding the rejections based on 35 U.S.C. § 112, first paragraph, applicants respectfully traverse and request reconsideration in view of the amended claims and the following remarks. The presently claimed invention is sufficiently described so as to enable one skilled in the art to

make and/or use the claimed invention. Applicant has provided ample guidance for the method claimed to permit one of ordinary skill in the art to make and use the invention described in the claims without undue experimentation. The Examiner has seemingly ignored the specification and focused only on the Examples. The Examples are but one aspect of the guidance provided in this application and the failure to consider the teachings in the specification ignores the totality of the Applicants' teachings and support for the claimed inventions. Note on page 4 of the Office Action that the Examiner refers only to the Examples as providing "guidance," and ignores the teachings of the specification on pages 7-20. Thus, the Patent Office cannot establish a *prima facie* case of non-enablement. It should be noted that as a matter of Patent Office practice, and consistent with statutory requirements, a specification disclosure which:

> contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi, 169 USPQ 367 (CCPA 1971). Furthermore:

> it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement made in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id at 370. The rejection fails to satisfy this standard as it has provided no substantiated reason to doubt the objective truth of the statements made by applicants in its specification as to the scope of its invention.

It is well-settled law that enablement is not precluded by the necessity for some experimentation. As stated in In re Wands, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988):

> the determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. (citations omitted) But the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction to which the experimentation should proceed.

It is submitted that one or ordinary skill in the art would know which experiments to conduct to practice the methods and make the plants of the present invention, especially in view of the contemporaneous literature in this field and in view of the specification. Thus, in combination with the level of skill of one of ordinary skill in the art and the absence of any evidence or reasoning of record which would support a finding that the disclosure is not enabling for the claims as presently written, it is submitted that a *prima facie* case of non-enablement has not been established.

Moreover, the Examiner's reference to applicants' disclosure regarding phosphinothricin is questioned. It is true that applicant and others have taught that direct selection on phosphinothricin does not work, but that is not the claimed invention. The relevance of the Examiner's statements in this regard are thus confusing as to whether the Examiner fully understands the claimed invention. Applicants' have described a method that first provides culturing in a "sublethal" amount of a plastid lethal compound followed by a selection step in a lethal amount of a plastid lethal compound. The 35 U.S.C. §112, first paragraph rejection must, therefore, be withdrawn.

Rejection under 35 USC § 102

Claims 13-14 and 16-22 stand rejected under 102(b) as being anticipated by Blowers et al. This rejection is respectfully traversed and reconsideration requested. Blowers does not teach or describe a method of placing a plastid lethal compound in a "sublethal concentration" in a media to permit cells to continue to grow and then followed by an application of a lethal amount of a plastid lethal compound. As the Examiner acknowledges on page 8 of the Office Action, Blowers "selects" for transformants as described on pages 51 and 69 and that is indicative of a lethal concentration of the selection agent. The concentration of glyphosate used by Blowers is at least 1mM and discloses concentrations up to at least 10mM. These are all plastid lethal concentrations. This is evidenced by reference to Applicants' Examples and the specification wherein a concentration of glyphosate at 100μM was determined to be lethal to plastids. Thus, the Examiner cannot equate "low" concentrations as a sublethal concentration as defined in the specification and as recited in the claims. Thus, Blowers et al. does not teach the claimed invention and this rejection must be withdrawn.

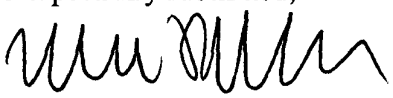
Rejection under 35 USC §103

Claims 12-22 stand rejected under 103(a) as being unpatentable over Blowers et al. in view of Daniell et al. As discussed above, Blowers et al does not teach the claimed invention. As acknowledged by the Examiner, Daniell is cited only for plastids containing a vector comprising an EPSPS cassette. Daniell et al does not teach, suggest or disclose the method of the claimed invention. This rejection must therefore be withdrawn.

Conclusion

Applicants respectfully request reconsideration on the merits of the application as a whole. The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



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Version with Markings to Show Changes Made

13. (amended) A method for obtaining a transplastomic plant comprising the steps of:

a) introducing into a plastid of a plant cell [plastid] a recombinant nucleic acid construct comprising a promoter functional in a plant cell plastid, a nucleic acid sequence encoding a protein providing for tolerance to a plastid lethal compound and a transcriptional termination region functional in a plant cell plastid,

b) placing said plant cell into which [having] said nucleic acid construct has been introduced on a first culture medium comprising a sublethal amount of a plastid lethal compound corresponding to said protein providing for tolerance for a period of time sufficient to permit said plant cell to replicate, and

c) placing said plant cell on a second culture medium comprising [a] said plastid lethal compound for a period of time sufficient to select plant cells capable of growing in the presence of said plastid lethal compound; and

d) regenerating a transplastomic plant from said plant cells that grow in said second culture medium.

14. (amended) The method according to Claim 13, wherein said nucleic acid sequence encodes for a protein[s] [selected from the group consisting of genes] providing tolerance to a herbicide[s], an inhibitor[s] of a plastid metabolic pathway[s], a protease[s], [and] or a nuclease[s].

16. (amended) The method according to Claim 13, wherein said plastid lethal compound is selected from the group consisting of a herbicide[s], a protease, a nuclease, and a plastid metabolic pathway inhibitor.

18. (amended) The method according to Claim 13, wherein said nucleic acid construct further comprises regions of plastid homology.